REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1, 13 and 19-20 are pending. Claims 1, 13 and 19 have been amended editorially. The amendment to claims 1 and 13 is supported by the original disclosure, for example, by original claims 7 and 18. Also, the results in Tables 2 and 3 on page 10 of Example 2 on pages 9-10 of the specification, for example, show the use of a sensitizer that increases the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer as recited in claims 1 and 13. New claim 20 is supported by the original disclosure, for example, at page 6, lines 22-23 of the specification. Claims 7-8 and 18 have been canceled without prejudice or disclaimer.

Claim rejections - 35 U.S.C. § 103

Claims 1, 8, and 13 are rejected as unpatentable over U.S. Patent Application Publication No. 2005/0106748 (Proffitt et al.). The features of claims 7 and 18 are included in claim 1. The features of claim 18 are included in claim 13. Claims 7 and 18 were not included in this rejection. Claim 8 has been canceled. Accordingly, the rejection is rendered moot. Applicant does not concede the correctness of the rejection.

Claim 7 is rejected under 35 USC 103(a) as being unpatentable over Proffitt et al. in view of Lau (EP 0,361,244). The rejection is rendered moot, as claim 7 has been canceled. Applicant does not concede the correctness of the rejection.

Claims 18 and 19 are rejected under 35 USC 103(a) as being unpatentable over Proffitt et al. in view of Albarella et al. (US 5,424,215). Applicant respectfully traverses the rejection.

The features of claim 18 are included in claim 1. Claim 1 recites that the protein assay indicator is used in the presence of a sensitizer, and that the sensitizer is a compound that increases the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer.

The advantageous effects of claim 1 are demonstrated, for example, in Example 2 on pages 9-13 of the specification. Table 3 provides results for Samples 1 and 3, which were

assayed in accordance with claim 1. Samples 2 and 4 also were assayed in accordance with claim 1, except that a sensitizer in accordance with claim 1 was not used. As shown in Table 3, Samples 1 and 3 exhibited a higher reflectance when the albumin concentration was negative (0.3 mg/dL of albumin) and a lower reflectance when the albumin concentration was positive (15 mg/dL of albumin), as compared to those of Samples 2 and 4. In other words, Samples 1 and 3 exhibited a higher reflectance differential between negative and positive urine as compared to that of Samples 2 and 4. These results demonstrate that a sensitizer in accordance with claim 1 can be used to provide a higher coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer, even where the albumin concentration is between 10 and 20 mg/dL in the urine sample.

The rejection concedes that Proffitt does not teach a sensitizer, but relies on Albarella for the use of a sensitizer. However, Albarella does not disclose or suggest the sensitizer as recited in claim 1.

In particular, Albarella indicates that conventional methods involving the use of test strips suffer from generating false positives due to the inherent limitation of the test strips being incapable of separating between trace concentrations of albumin (albumin concentrations of about 15 mg/dL) and negative albumin concentration. Albarella explains at col. 1, lines 45-50 that certain polycarbonate compounds can be added to lower the coloration sensitivity of the protein indicator, and does not disclose or suggest a sensitizer that increases the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer as recited in claim 1. In fact, Albarella appears to suggest the use of a compound that achieves the opposite of the requirements of claim 1.

The rejection contends that it would have been obvious to modify Proffitt in view of Albarella to utilize polypropylene glycol as a sensitizer in order to reduce the reactivity of a reagent paper and to decrease false positives as taught by Albarella. However, Proffitt and Albarella do not provide any guidance or experimental data showing that polypropylene glycol could be used to increase the coloration sensitivity of the protein assay indicator with

respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer, even where the albumin concentration is between 10-20 mg/dL in the urine sample as demonstrated, for example, in the experimental work in the specification. In fact, Albarella teaches that the addition of polypropylene glycol achieves just the opposite when assaying a urine sample containing albumin in an amount between 10-20 mg/dL in order to decrease the incidences of false positives.

The features of claim 18 also are included in claim 13. Claim 13 recites that the test piece further contains a sensitizer, and that the sensitizer is a compound that increases the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer.

It is clear from the above discussion that Proffitt and Albarella do not disclose or suggest a sensitizer that increases the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution as compared to the coloration sensitivity of the protein assay indicator with respect to albumin present in the solution in the absence of the sensitizer as recited in claim 13. Accordingly, claim 13 and its dependent claims are patentable over Proffitt and Albarella taken alone or together.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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